

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day-17-0051; Docket No. ATSDR-2017-0004]

Proposed Data Collection Submitted for Public Comment and

Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry

(ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

Registry (ATSDR), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed request to extend the information collect project titled "Assessment of Chemical Exposures (ACE) Investigations." The purpose of ACE Investigations is to focus on performing rapid epidemiological assessments to assist state, regional, local, or tribal health departments (the requesting agencies) to respond to or prepare for acute chemical releases.

DATES: Written comments must be received on or before

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2017-0004 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection
 Review Office, Centers for Disease Control and
 Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta,
 Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post all relevant comments, without change, to Regulations.gov, to include any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through
the Federal eRulemaking portal (Regulations.gov) or by U.S.
mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact

Leroy A. Richardson, Information Collection Review Office,
Centers for Disease Control and Prevention, 1600 Clifton
Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-6397570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Assessment of Chemical Exposures (ACE) Investigations (OMB Control Number 0923-0051; expiration 3/31/2018) - Revision - Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting to revise "Assessment of Chemical Exposures (ACE) Investigations" information collection project and seek a three-year OMB approval to assist state and local health departments after toxic substance spills or chemical incidents. The OMB Control number for this information collection expires 3/31/2018. We are renaming the form previously titled the Rapid Response Registry Form as the ACE Short Form. This revision better describes that we use the ACE Short Form in time-limited investigations where longer surveys are not possible. We do not use the form to establish registries. In addition, we are removing two insurance questions from the ACE Short Form, as we do not ask in the longer surveys and have never been asked as part of an ACE Investigation. There are no changes to the requested burden hours.

ATSDR has successfully completed three investigations to date. With the uses of this valuable mechanism, ATSDR would like to continue this impactful information

collection. See below a brief summary of information collections approved under this tool:

- During 2015, in U.S. Virgin Islands there was a methyl bromide exposure at a condominium resort. Under this ACE investigation, awareness among pest control companies that methyl bromide currently prohibited in the homes and other residential settings.

 Additionally, awareness for clinicians about the toxicologic syndrome caused by exposure to methyl bromide and the importance of notifying first responders immediately when they have encountered contaminated patients.
- During 2016, ACE team conducted a rash investigation in Flint, Michigan. Persons exposed to Flint municipal water and had current or worsening rashes surveyed and referred too free dermatologist screening if desired. Findings revealed that when the city was using water from the Flint River, there were large swings in chorine, pH, and hardness, which could be one possible explanation for the eczema-related rashes.
- During 2016, ACE team also conducted a follow-up investigation for people whom been exposed to the Flint municipal water and sought care from the free

dermatologists. Data analysis for this project is in process and results are pending. However, the follow-up interviews resulted in improving the exam and referral processes that were still on going at the time.

The ACE investigations focus on performing rapid epidemiological assessments to assist state, regional, local, or tribal health departments (the requesting agencies) to respond to or prepare for acute chemical releases.

The main objectives for performing these rapid assessments are to:

- Characterize exposure and acute health effects of respondents exposed to toxic substances from discrete, chemical releases and determine their health statuses;
- 2. Identify needs (i.e. medical and basic) of those exposed during the releases to aid in planning interventions in the community;
- 3. Assess the impact of the incidents on health services use and share lessons learned for use in hospital, local, and state planning for chemical incidents; and

4. Identify cohorts may be followed and assessed for persistent health effects resulting from acute releases.

Because each chemical incident is different, it is not possible to predict in advance exactly what type of and how many respondents will be consented and interviewed too effectively evaluate the incident. Respondents typically include, but are not limited to emergency responders such as police, fire, hazardous material technicians, emergency medical services, and personnel at hospitals where patients from the incident were treated. Incidents may occur at businesses or in the community setting; therefore, respondents may also include business owners, managers, workers, customers, community residents, pet owners, and those passing through the affected area.

The multidisciplinary ACE team consisting of staff from ATSDR, the Centers for Disease Control and Prevention (CDC), and the requesting agencies that will be collecting data. ATSDR has developed a quickly tailored series of draft survey forms used in the field to collect data that will meet the goals of the investigation. ATSDR collections will be administered based on time permitted and urgency. For example, it is preferable to administer the general survey to as many respondents as possible. However, if

there are time constraints, the shorter household survey or the ACE Short Form may be administered instead. The individual surveys collect information about exposure, acute health effects, health services use, medical history, needs resulting from the incident, communication during the release, health impact on children and pets, and demographic data. Hospital personnel are asked about the surge, response and communication, decontamination, and lessons learned.

Depending on the situation, data collected by face-to-face interviews, telephone interviews, written surveys, mailed surveys, or on-line surveys can be consider collected. Medical and veterinary charts may also be consider for review. In rare situations, an investigation might involve collection of clinical specimens.

ATSDR anticipates up to four ACE investigations per year. The number of participants has ranged from 30-715, averaging about 300 per year. Therefore, the total annualized estimated burden will be 591 hours per year. Participation in ACE investigations is voluntary and there are no anticipated costs to respondents other than their time.

Estimated Annualized Burden Hours

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hours) | Total Burden (in hours) |
|---|--|-----------------------|--|-------------------------------------|-------------------------------|
| Residents, first | General Survey | 800 | 1 | 30/60 | 400 |
| responders, business owners, employees, customers | ACE Short Form | 50 | 1 | 7/60 | 6 |
| Residents | Household Survey | 120 | 1 | 15/60 | 30 |
| Hospital staff | Hospital Survey | 40 | 1 | 30/60 | 20 |
| Staff from state, local, or | Medical Chart Abstraction Form | 250 | 1 | 30/60 | 125 |
| tribal health agencies | Veterinary Chart Abstraction Form | 30 | 1 | 20/60 | 10 |
| | | | | Total | 591 |

Leroy A. Richardson,

Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

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